INTERNATIONAL
ITC
TECHNIDYNE
CORPORATION
8 Olsen Avenue ▼ Edison, NJ 08820
Toll Free Phone: (800) 631-5945
Phone: (732) 548-5700 FAX: (732) 632-9299

JUL - 2 2001

510 (k) Summary

ProTime® Microcoagulation System - ProTime 3 Cuvette

This summary of safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K010599

Prepared: February 27, 2001

Submitted by: John Clay
International Technidyne Corp.
6 Olsen Ave.
Edison, NJ 08820
(732-548-5700) Ext. 265 (732-548-2325) Fax

Device Name

Common / Usual Name: Prothrombin Time Test System
Product Name: ProTime Microcoagulation System – ProTime 3 Cuvette

Predicate Device

The modifications to the ProTime Microcoagulation System described herein are substantially equivalent to the previously cleared and CLIA waived ProTime Microcoagulation system under K951072/S1 (10/27/95) for professional use and K961835 (03/12/97) for home use.

Device Description and Technological Characteristics

The ProTime Microcoagulation System consists of a portable battery operated instrument and disposable cuvette for the determination of prothrombin time from fingerstick whole blood or anticoagulant-free venous whole blood. This system measures prothrombin time (PT) using fibrin clot formation and detection.

The instrument draws a precise volume of blood into the test channel of the cuvette, which contains thromboplastin, stabilizers and preservatives. An array of LED's detects the motion of the sample/reagent mixtures as they move through precision restrictions in the cuvette channels. The blood is pumped back and forth until a clot begins to form,

obstructing the channels and slowing the flow of the blood sample. The instrument detects a clot when the blood movement decreases below a predetermined rate. After the clot is detected, the PT result is displayed on the screen, represented by both PT seconds and the INR (International Normalized Ratio).

Modifications to the ProTime System

The modifications to the ProTime system include a software revision to the instrument and physical modifications to the test cuvette and the blood sample collection cup to accommodate a smaller volume blood sample. The modified system substantially reduces the blood sample volume required, which is seen as an advantage by many of the ProTime system users. The ProTime instrument containing the modified instrument software has the capability to perform a PT assay using the standard 5-channel cuvette or the new 3-channel cuvette. The modifications to the ProTime System described do not change the indications for use or the fundamental technology used in the previously cleared system.

Software

The instrument software has been modified to recognize and perform testing using either the new 3-channel or the previously cleared 5-channel cuvette. The modified software recognizes a unique barcode identifier, which is placed on each cuvette. Additional modifications include customized testing specifications and pumping profile specific to the 3-channel system.

INR Determination

The ProTime Microcoagulation System measures whole blood clotting time and converts this result to an INR value through a conversion equation contained in the barcode of each cuvette. The conversion equation for the ProTime3 is established via regression analysis of external clinical evaluations, comparing the ProTime3 to the laboratory result (n=229 paired samples), where whole blood samples were collected at independent clinical sites. Whole blood samples were tested with the ProTime Microcoagulation System and at the local lab. Plasma was frozen and sent to a reference lab for repeat testing. The conversion equation for the 3-channel (low volume assay) has been adjusted for optimal accuracy when compared to the plasma laboratory test using plasma collected from 3.2% sodium citrate tubes.

Physical

The predicate standard ProTime system consists of a 5-channel cuvette: two channels which perform a level I and level II control with each assay and three replicate test channels for measuring the sample PT. The cuvette modifications include the elimination of two functional PT test channels, leaving one PT test channel and the two (level I and level II) reagent control channels. To accommodate a lower blood volume requirement, the cross sectional area of the three channels was reduced approximately 30%. The physical layout of the cuvette has been conserved. The combination of the reduction in channels and channel area reduces the required blood sample by approximately 50%. The blood sample collection cup has also been reduced in size to accommodate the reduced blood sample volume and for rapid identification of the required blood sample.

Reagent Formulation
The prothrombin reagent used in the test cuvette remains consistent with the previously marketed ProTime System. The ratio of blood sample tested to reagent in the cuvette has been conserved.

Instrument Hardware
All of the instrument hardware including the clot detection mechanism, circuit boards, heaters etc... remain the same.

User Interface
The user interface for both the clinician and the patient self-testers (Prescription Home Use) remains consistent with the previously cleared system.

Statement of Intended Use

The ProTime Microcoagulation System / ProTime 3 Test Cuvette is intended for use for the quantitative determination of prothrombin time from fingerstick whole blood or anticoagulant-free venous whole blood. The Protime Microcoagulation System is intended for either professional use or for patient self-testing in the management of patients treated with oral anticoagulants.

For In Vitro Diagnostic Use Only

Summary of Performance Data

The following INR correlations were calculated from clinical data for fingerstick whole blood and venous samples:

	Fingerstick	Venous
3-Channel (low volume assay) vs Local Lab	r=0.93, n=229 y=1.00x+0.18	r=0.92, n=219 y=0.91x+0.30
3-Channel (low volume assay) vs Reference lab	r=0.95, n=229 y=1.05x +0.07	r=0.95, n=219 y=0.97x +0.19
3-Channel (low volume assay) vs 5-Channel	r= 0.94, n=229 y = 1.02x–0.14	r=0.95, n=214 y=0.97x-0.08

Note: Laboratory results were obtained using plasma collected in 3.2% sodium citrate as recommended by NCCLS standards (H21-A3, Vol. 18 No. 20; Collection, Transport and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline – Third Edition.

In House Precision Testing

Precision testing was conducted on both the ProTime 3 and predicate ProTime using two levels of standard control plasma substrate preparations, which have been selected to represent normal donors (Level I) and patients on oral anticoagulant therapy (Level III).

ProTime 3

PRECISION		n	Mean INR	SD
Level I	within day	18	0.9	0.07
	day-to-day (5 days)	4/day	0.9	0.12
Level III	within day	20	4.0	0.19
	day-to-day (5 days)	4/day	4.2	0.22

Standard ProTime

PRECISION		n	Mean INR	SD
Level I	within day	17	0.9	0.06
	day-to-day (5 days)	4/day	1.0	0.08
Level III	within day	19	3.2	0.19
	day-to-day (5 days)	4/day	3.2	0.12

Conclusion:

The technology employed and intended use of the modified ProTime System is substantially equivalent to the Predicate ProTime System. The modified 3-channel cuvette provides the user with an alternate means for performing the prothrombin time test using a significantly reduced blood sample.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL - 2 2001

Mr. John Clay
Regulatory Affairs Manager
International Technidyne Corporation
8 Olsen Avenue
Edison, NJ 08820

Re: 510(K) Number: K010599
Trade/Device Name: ProTime Microcoagulation System / ProTime 3 Test Cuvette
Regulation Number: 864.7750
Regulatory Class: II
Product Code: GJS
Dated: June 1, 2001
Received: June 4, 2001

Dear Mr. Clay:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (If Known): K010599

Device Name: ProTime Microcoagulation System / ProTime 3 Test Cuvette
Indications for Use:

The ProTime Microcoagulation System / ProTime 3 Test Cuvette is intended for use for the quantitative determination of prothrombin time from fingerstick whole blood or anticoagulant-free venous whole blood. The Protime Microcoagulation System is intended for either professional use or for patient self-testing in the management of patients treated with oral anticoagulants.

For In Vitro Diagnostic Use Only

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K010599

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over- the- Counter Use_____
Per 21 CFR 801.109

(Optional Format 1-2-96)